

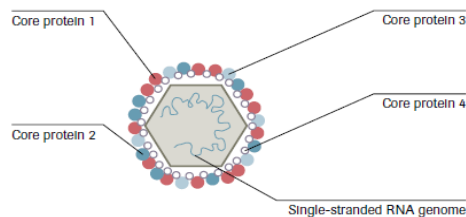
Elecsys® Hepatitis Assays

Helping detect and/or diagnose acute liver infection and inflammation due to hepatitis A virus (HAV), hepatitis B virus (HBV) or hepatitis C virus (HCV)

Elecsys Hepatitis Acute Panel assays—consistent 18 minute turnaround time, 28 day calibration frequency (7 day-same reagent onboard), 4-8 weeks* on board stability, small sampling volume required (110µL for the four assays combined).

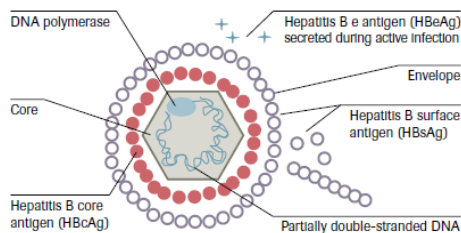
- Integrated solution for accurate comprehensive acute viral hepatitis testing
- Fast, convenient, and efficient method for the sample analysis

Acute Hepatitis Panel^{1,2,3}



Anti-HAV, IgM

A positive test is usually considered diagnostic for acute hepatitis A in a person with signs and symptoms.

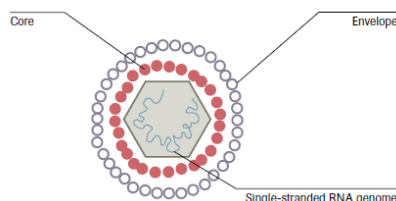


HBsAg

HBsAg is the earliest indicator of an acute infection but may also be present in the blood of those chronically infected

Anti-HBc, IgM

Anti-HBc, IgM is the first antibody produced in response to a hepatitis B infection and, when detected, may indicate an acute infection. It may also be present in people with chronic hepatitis B when flares of disease activity occur.



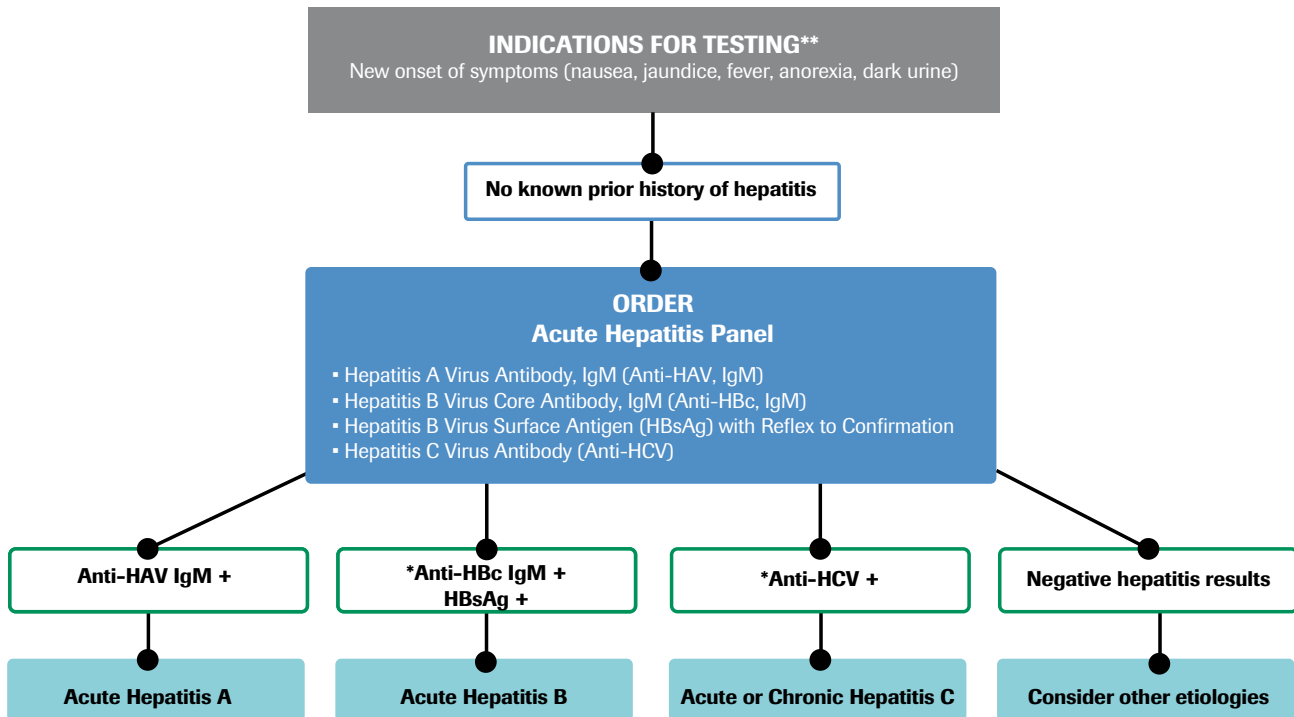
Anti-HCV

Anti-HCV cannot distinguish between an active or previous infection. If positive, it is typically followed up with other tests to determine if the infection is a current one.

The Roche cobas systems provide a safe, convenient, and efficient means of testing for viral hepatitis and other infectious diseases.

*Anti-HAV, 7 days if continuously stored onboard the analyzer at 20-25°C or 4 weeks when stored alternatively in the refrigerator and on the analyzer, with the total time onboard on the analyzers not exceeding 40 hours.

Hepatitis Screening Algorithm



*Presumptive evidence of infection. Follow CDC recommendations for supplemental testing

Interpretation of results†

Anti-HAV IgM +	HBsAg	Anti-HBc IgM	Anti-HCV	Interpretation
Positive	Negative	Negative	Negative	Acute Hepatitis A
Negative	Positive	Positive	Negative	Acute Hepatitis B
Negative	Positive	Negative	Negative	Chronic Hepatitis B
Negative	Negative	Positive	Negative	Acute Hepatitis B; quantity of Hepatitis B surface antigen is too low to detect
Negative	Negative	Negative	Positive	Acute or chronic Hepatitis C; additional testing required

† <http://labtestsonline.org/understanding/analytes/hepatitis-panel/tab/test/> (accessed 3/9/18)

The following CPT® codes may be used to describe applicable hepatitis testing performed via non-modified FDA-cleared cobas® systems/analyzers and reagents/kits:

Acute Hepatitis Panel	80074 (This panel must include the following)
Hepatitis A antibody (HAAb), IgM antibody	86709
Hepatitis B core antibody (HBcAb), IgM antibody	86705
Hepatitis B surface antigen (HBsAg)	87340
Hepatitis C antibody	86803

Note: CPT panels were developed for coding purposes only and should not be interpreted as clinical parameters. Providers are not required to report CPT panel codes. Testing must be appropriate and necessary for an individual patient.

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Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256
usdiagnostics.roche.com

- 1 Lemon, S.M. (1997). Type A viral hepatitis: epidemiology, diagnosis, and prevention. *Clin Chem*. 43, 1494 –1499
- 2 Elgouhari, H.M., et al. (2008). Hepatitis B infection: understanding its epidemiology, course and diagnosis. *Cleve Clin J Med*. 75, 881–889
- 3 Hoofnagle, J.H. (2002). Course and outcome of hepatitis C. *Hepatology* 36, S21–S29

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Regulatory Approval	David Piechocki Regulatory 13-Apr-2018 12:52:47 GMT+0000
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Medical Approval	Ursula Klause Medical 03-Jun-2018 22:57:48 GMT+0000
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